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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/785,162 | 02/23/2004 | Assaf Govari | BIO-5042 | 8493 |
| 27777 | 7590 | 05/06/2010 | EXAMINER | |
| PHILIP S. JOHNSON | | | CWERN, JONATHAN | |
| JOHNSON & JOHNSON | | | | |
| ONE JOHNSON & JOHNSON PLAZA | | | ART UNIT | PAPER NUMBER |
| NEW BRUNSWICK, NJ 08933-7003 | | | 3737 | |
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| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 05/06/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com
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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/785,162 | GOVARI ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan G. Cwern | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 March 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 18-21, 23-24, 35-37, 39-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (5,808,665) in view of Webster (6,123,699) and Vesely (6,246,898).

Green discloses an apparatus and method for use with a steerable catheter (268R, 268L; col. 10, lines 47-61) with hand controllers (72R, 72L) and a deflectable distal tip. Green discloses an end-effector (170, 270R, 270L; col 2, lines 3-7) that moves in response to the hand-operated control means (col 9, lines 10-21). Green discloses use of a servomechanism that includes computer (42) that is well known in the robotic art (col 11, lines 44-47). Green discloses the control section as containing motors and linkages which operate the insertion section with five or more degrees of freedom (abstract, lines 12-14) and is also capable of pivoting with one or more degrees of freedom (abstract, lines 18-20). This would encompass the six dimensions of position and orientation information of the present invention. Green discloses pivotal movement of the distal tip in any direction, which would include rolling or jiggling, as well as axial movement of the outer section (150L2) into and out of the inner section (150L1) as well

as rotation about the longitudinal axis (column 8, line 45-column 9, line 37 and Figure 11). Green does not disclose a thumb control explicitly.

Webster discloses sliding a button longitudinally in the length of a slot by means of thumb pressure within a control handle (col 8, lines 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to combine the steerable catheter assembly of Green with the thumb control of Webster for the purpose of manually manipulating the catheter tip in a desired path.

The modified invention of Green discloses the invention substantially as claimed except for the apparatus comprising a computer pointing device and a position sensor, wherein the controller is adapted to receive the position signal. However, Green does recognize that the system can employ well known mechanisms such as optical or electromagnetic position encoders (column 11, lines 25-27). As Green does not go into specific details in regards to these features, the Vesely reference is provided to further teach these features.

Vesely discloses a steerable catheter with position tracking and method for using (abstract, lines 2-6) and a computer pointing device, wherein a robotic controller receives the position signal and responds thereto (column 25, line 28-column 26, 48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to have combined the modified steerable catheter of Green with the position tracking, computer pointing device, and robotic control of Vesely for the

purpose of providing more accurate guided therapies.

Response to Arguments

Applicant's arguments filed 3/29/10 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to applicant's arguments that Green does not disclose the thumb control, the examiner would like to point out that the Webster reference was provided to teach the thumb control. Furthermore, controlling a steerable catheter is clearly disclosed by Green in column 10, line 50-column 11, line 8, as opposed to applicant's position that Green is merely controlling a pair of movable jaws.

In regards to applicant's arguments regarding claims 13, 18, 35, and 39, examiner respectfully disagrees. These claims describe specific motions of how the catheter can be steered. As stated in the rejection, Green discloses that the control section can operate the insertion section with six degrees of freedom, essentially in all directions and rotations, and including rolling or jiggling. This is also described in Green in column 8, line 45-column 9, line 37 and Figure 11. It would be obvious to navigate

the device in any direction depending on what location in the body the device is being guided to.

The rejection in view of the Plicchi et al. reference is withdrawn in view of applicant's arguments and the declaration filed 3/29/10.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737